

Response to Office Action of: 11/29/2005
Response Dated: 02/28/2006
Title: Custom Prosthetic Liner Manufacturing System And Method

App. No.: 10/724,526
Inventor: R. Arbogast et al.
Examiner: Charles R. Kasenge

Amendment(s) to the Claims

The following listing of claims replaces all prior versions and listings of claims in the present application:

Listing of Claims:

Claim 1 (amended): A system for producing a custom prosthetic liner of flexible polymeric material, comprising:

a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

a processing device for generating a 3-dimensional electronic liner model using said 3-dimensional shape captured by said shape capture apparatus, said processing device optionally adapted to generate a 3-dimensional electronic residual limb model;

a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner;

an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both; and

a mold for receiving and containing an amount of said flexible polymeric material, said mold incorporating said at least one custom mold component; and

a molding machine for producing said custom prosthetic liner from a said mold incorporating said at least one custom mold component.

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Claim 2 (original): The system of claim 1, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

Claim 3 (original): The system of claim 1, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 4 (original): The system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

Claim 5 (original): The system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

Claim 6 (original): The system of claim 1, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 7 (original): The system of claim 1, wherein said at least one custom mold component is produced from said data by a computer-controlled machining device.

Claim 8 (original): The system of claim 1, wherein said at least one custom mold component is created from a closed-cell foam material.

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Claim 9 (original): The system of claim 1, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 10 (original): The system of claim 9, wherein said mold cavity is selected based on its size.

Claim 11 (original): The system of claim 1, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 12 (original): The system of claim 1, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 13 (original): The system of claim 12, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 14 (original): The system of claim 1, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 15 (original): The system of claim 1, further comprising the ability to modify the shape of either or both of said 3-dimensional electronic models to accommodate particular features of said residual limb in said custom prosthetic liner.

Claim 16 (original): The system of claim 1, further comprising the ability to select liner materials and material properties.

Claim 17 (original): The system of claim 1, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 18 (original): The system of claim 17, wherein the number, location, and orientation of said accessories may be specified.

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Claim 19 (original): The system of claim 17, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 20 (original): The system of claim 18, wherein said additives include anti-microbial substances.

Claim 21 (original): The system of claim 1, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

Claim 22 (amended): A method for producing a custom flexible polymeric prosthetic liner, comprising:

- using a shape capture apparatus to capture the 3-dimensional shape of an amputee's residual limb;

- using a processing device to generate a 3-dimensional electronic liner model from the captured shape;

- optionally, using said processing device to generate a 3-dimensional electronic residual limb model from the captured shape;

- providing a means of furnishing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner;

- creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both; and

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providing a mold adapted to receive and contain an amount of flexible polymeric material, said mold incorporating said at least one custom mold component; and

using a molding machine to produce said custom prosthetic liner from a said mold incorporating said at least one custom mold component.

Claim 23 (original): The method of claim 22, wherein said means for capturing the 3-dimensional shape of an amputee's residual limb is a multiple image detector shape capture device.

Claim 24 (original): The method of claim 22, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 25 (original): The method of claim 22, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

Claim 26 (original): The method of claim 22, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

Claim 27 (original): The method of claim 22, wherein data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb

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model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 28 (original): The method of claim 22, wherein said at least one custom mold component is produced from said data by a computer-controlled machining device.

Claim 29 (original): The method of claim 22, wherein said at least one custom mold component is created from a closed-cell foam material.

Claim 30 (original): The method of claim 22, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 31 (original): The method of claim 30, wherein said mold cavity is selected based on its size.

Claim 32 (original): The method of claim 22, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 33 (original): The method of claim 22, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 34 (original): The method of claim 33, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 35 (original): The method of claim 22, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 36 (original): The method of claim 22, further comprising providing the ability to manipulate the shape of either or both of said 3-dimensional electronic liner and residual limb models to accommodate particular features of said residual limb in said custom prosthetic liner.

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Claim 37 (original): The method of claim 22, further comprising providing the ability to select liner materials and material properties.

Claim 38 (original): The method of claim 22, further comprising providing the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 39 (original): The method of claim 38, wherein the number, location, and orientation of said accessories may also be specified.

Claim 40 (original): The method of claim 38, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 41 (original): The method of claim 40, wherein said additives include anti-microbial substances.

Claim 42 (original): The method of claim 22, further comprising a providing a means of communication with an automated system for configuring and purchasing a medical device.

Claim 43 (amended): A system for producing a custom prosthetic liner of flexible polymeric material, comprising:

- a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

- a storage means in communication with said shape capture apparatus for temporarily storing data associated with said 3-dimensional shape of an amputee's residual limb;

- a means of providing said data to a facility equipped to produce said custom prosthetic liner;

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a means at said facility for associating prosthetic liner parameters with said data;

an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional shape of an amputee's residual limb and said prosthetic liner parameters; and

a mold for receiving and containing an amount of said flexible polymeric material, said mold incorporating said at least one custom mold component; and

a molding machine for forming said custom prosthetic liner from a said mold incorporating said at least one custom mold component.

Claim 44 (original): The system of claim 43, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

Claim 45 (original): The system of claim 43, wherein said storage means stores said data associated with the captured 3-dimensional shape of an amputee's residual limb on a machine readable medium for subsequent delivery to said facility equipped to produce said custom liner.

Claim 46 (original): The system of claim 43, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is remotely transmitted to said facility equipped to produce said custom liner.

Claim 47 (original): The system of claim 43, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

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Claim 48 (original): The system of claim 43, further comprising a processing device in communication with said shape capture apparatus, said processing device for generating a 3-dimensional electronic model of said residual limb from said 3-dimensional shape captured by said shape capture apparatus

Claim 49 (original): The system of claim 48, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 50 (original): The system of claim 43, further comprising a means for generating numerical data representative of said 3-dimensional model.

Claim 51 (original): The system of claim 50, wherein said numerical data is generated after delivery of said data associated with the captured 3-dimensional shape of an amputee's residual limb to said facility equipped to produce said custom liner.

Claim 52 (original): The system of claim 50, wherein said numerical data is generated by said shape capture apparatus or a device in communication with said shape capture apparatus, and said numerical data is subsequently provided to said facility equipped to produce said custom liner.

Claim 53 (original): The system of claim 43, wherein said at least one custom mold component is produced by a computer-controlled machining device.

Claim 54 (original): The system of claim 43, wherein said at least one custom mold component is created from a closed-cell foam material.

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Claim 55 (original): The system of claim 43, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 56 (original): The system of claim 55, wherein said mold cavity is selected based on its size.

Claim 57 (original): The system of claim 43, wherein said at least one custom mold component is a custom mold cavity for use with a custom or common mold cavity.

Claim 58 (original): The system of claim 43, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 59 (original): The system of claim 58, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 60 (original): The system of claim 43, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 61 (original): The system of claim 43, further comprising the ability to manipulate said data associated with said 3-dimensional shape of an amputee's residual limb in order to accommodate particular features of said residual limb in said custom prosthetic liner.

Claim 62 (original): The system of claim 43, further comprising the ability to select liner materials and material properties.

Claim 63 (original): The system of claim 43, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 64 (original): The system of claim 63, wherein the number, location, and orientation of said accessories may also be specified.

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Claim 65 (original): The system of claim 63, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 66 (original): The system of claim 65, wherein said additives include anti-microbial substances.

Claim 67 (original): The system of claim 43, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

Claim 68 (amended): A method of producing a custom flexible polymeric prosthetic liner, comprising:

- using a shape capture apparatus to capture the 3-dimensional shape of an amputee's residual limb;

- providing a storage means in communication with said shape capture apparatus for temporarily storing data associated with said 3-dimensional shape of an amputee's residual limb;

- providing a means of furnishing said data to a facility equipped to produce said custom prosthetic liner;

- providing a means at said facility for associating prosthetic liner parameters with said data;

- creating at least one custom mold component from said data associated with said 3-dimensional shape of an amputee's residual limb and said prosthetic liner parameters; and

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providing a mold for receiving and containing an amount of flexible polymeric material, said mold incorporating said at least one custom mold component; and

using a molding machine to produce said custom prosthetic liner from a said mold incorporating said at least one custom mold component.

Claim 69 (original): The method of claim 68, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

Claim 70 (original): The method of claim 68, wherein said storage means stores said data associated with the captured 3-dimensional shape of an amputee's residual limb on a machine readable medium for subsequent delivery to said facility equipped to produce said custom liner.

Claim 71 (original): The method of claim 68, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is remotely transmitted to said facility equipped to produce said custom liner.

Claim 72 (original): The method of claim 68, wherein said data associated with the captured 3-dimensional shape of an amputee's residual limb is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 73 (original): The method of claim 68, further comprising providing a processing device in communication with said shape capture apparatus, said processing device for generating a 3-dimensional electronic model of said residual limb from said 3-dimensional shape captured by said shape capture apparatus

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Claim 74 (original): The method of claim 68, wherein said processing device consists of a computer program in combination with a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 75 (original): The method of claim 68, further comprising a means for generating numerical data representative of said 3-dimensional model.

Claim 76 (original): The method of claim 75, wherein said numerical data is generated after delivery of said data associated with the captured 3-dimensional shape of an amputee's residual limb to said facility equipped to produce said custom liner.

Claim 77 (original): The method of claim 75, wherein said numerical data is generated by said shape capture apparatus or a device in communication with said shape capture apparatus, and said numerical data is subsequently provided to said facility equipped to produce said custom liner.

Claim 78 (original): The method of claim 68, wherein said at least one custom mold component is produced by a computer-controlled machining device.

Claim 79 (original): The method of claim 68, wherein said at least one custom mold component is created from a closed-cell foam material.

Claim 80 (original): The method of claim 68, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 81 (original): The method of claim 80, wherein said mold cavity is selected based on its size.

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Claim 82 (original): The method of claim 68, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 83 (original): The method of claim 68, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 84 (original): The method of claim 83, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 85 (original): The method of claim 68, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 86 (original): The method of claim 68, further comprising the ability to manipulate the data associated with said 3-dimensional shape of an amputee's residual limb to accommodate particular features of said residual limb in said custom prosthetic liner.

Claim 87 (original): The method of claim 68, further comprising providing the ability to select liner materials and material properties.

Claim 88 (original): The method of claim 68, further comprising providing the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 89 (original): The method of claim 88, wherein the number, location, and orientation of said accessories may also be specified.

Claim 90 (original): The method of claim 88, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

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Claim 91 (original): The method of claim 90, wherein said additives include anti-microbial substances.

Claim 92 (original): The method of claim 68, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

Claim 93 (amended): A system for producing a custom prosthetic liner of flexible polymeric material, comprising:

- a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

- a processing device running a computer program for generating a 3-dimensional electronic residual limb model from said 3-dimensional shape captured by said shape capture apparatus, said processing device and computer program further adapted to generate a 3-dimensional electronic liner model from said residual limb model and input liner parameters;

- an interface for allowing a user of said system to operate said computer program to modify said 3-dimensional electronic residual limb model, said 3-dimensional electronic liner model, or both, if so desired;

- an interface for allowing a user of said system to specify liner parameters;

- optionally, an interface for allowing a user of said system to communicate with a separate system and computer program that facilitates the automatic configuration and purchasing of a medical device;

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a storage device for temporarily storing data associated with said 3-dimensional electronic residual limb model and said 3-dimensional electronic liner model;

a transmission device for allowing data associated with a finalized version of said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to be remotely sent to a manufacturing facility equipped to produce said custom prosthetic liner;

a means at said manufacturing facility for receiving said data associated with said finalized version of said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, and for reading said data or converting said data into a readable form;

an apparatus for creating at least one custom mold component from said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both; and

a mold for receiving and containing an amount of said flexible polymeric material, said mold incorporating said at least one custom mold component; and

a molding machine for forming said custom prosthetic liner from a said mold incorporating said at least one custom mold component.

Claim 94 (original): The system of claim 93, wherein said shape capture apparatus employs a plurality of spaced-apart image detectors.

Claim 95 (original): The system of claim 93, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop

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computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 96 (original): The system of claim 93, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility via the Internet.

Claim 97 (original): The system of claim 93, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

Claim 98 (original): The system of claim 93, wherein said means for temporarily storing said data associated with said 3-dimensional electronic liner model and said 3-dimensional electronic residual limb model is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

Claim 99 (original): The system of claim 93, wherein said transmission means is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth[®] card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

Claim 100 (original): The system of claim 93, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 101 (original): The system of claim 100, wherein said mold cavity is selected based on its size.

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Claim 102 (original): The system of claim 93, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 103 (original): The system of claim 93, further comprising the ability to use said computer program to select liner materials and material properties.

Claim 104 (original): The system of claim 93, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

Claim 105 (original): The system of claim 104, wherein the number, location, and orientation of said accessories may also be specified.

Claim 106 (original): The system of claim 104, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 107 (original): The system of claim 106, wherein said additives include anti-microbial substances.

Claim 108 (original): The system of claim 93, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 109 (original): The system of claim 108, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 110 (amended): A system for producing a custom prosthetic liner that allows an amputee with a residual limb of changed shape and/or size to continue wearing an existing prosthetic socket, comprising:

a shape capture apparatus for capturing a 3-dimensional shape of said amputee's residual limb;

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a shape capture apparatus for capturing a 3-dimensional shape of the interior of said existing prosthetic socket;

a processing device, said processing device running a computer program for generating a 3-dimensional electronic liner model by comparing the captured 3-dimensional shapes of said amputee's residual limb and said interior of said existing prosthetic socket, calculating a difference in size and/or shape between the outer surface of said residual limb and the interior surface of said existing prosthetic socket, and automatically adjusting the thickness of said liner model as needed to make up for said difference in size and/or shape;

an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired;

a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a manufacturing facility equipped to produce said custom prosthetic liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

Claim 111 (original): The system of claim 110, wherein said shape capture apparatus for capturing the 3-dimensional shape of said residual limb is also used to capture the 3-dimensional shape of the interior of said existing prosthetic socket.

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Claim 112 (original): The system of claim 110, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 113 (original): The system of claim 110, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is provided to said manufacturing facility via the Internet.

Claim 114 (original): The system of claim 110, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

Claim 115 (original): The system of claim 110, further comprising a storage means for temporarily storing data associated with the shape of said residual limb and said 3-dimensional electronic liner model.

Claim 116 (original): The system of claim 115, wherein said storage means is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

Claim 117 (original): The system of claim 110, further comprising a transmission device for remotely transmitting said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to said manufacturing facility.

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Claim 118 (original): The system of claim 117, wherein said transmission device is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth® card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

Claim 119 (original): The system of claim 110, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 120 (original): The system of claim 110, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 121 (original): The system of claim 110, wherein said computer program also generates a viewable 3-dimensional electronic model of said existing prosthetic socket interior.

Claim 122 (original): The system of claim 110, further comprising the ability to use said computer program to select liner materials and liner material properties.

Claim 123 (original): The system of claim 110, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

Claim 124 (original): The system of claim 123, wherein the number, location, and orientation of said accessories may also be specified.

Claim 125 (original): The system of claim 123, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 126 (original): The system of claim 125, wherein said additives include anti-microbial substances.

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Claim 127 (original): The system of claim 110, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 128 (original): The system of claim 127, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 129 (amended): A system for producing a custom prosthetic liner that allows the residual limb of an amputee to be custom fit to a generic prosthetic socket, comprising:

- a shape capture apparatus for capturing the 3-dimensional shape of an amputee's residual limb;

- socket data representative of the 3-dimensional shape of an interior of said a generic prosthetic socket;

- a processing device, said processing device running a computer program for generating a 3-dimensional electronic liner model by comparing the captured 3-dimensional shape of said amputee's residual limb and said interior of said generic prosthetic socket, calculating a difference in size and/or shape between the outer surface of said residual limb and said interior surface of said generic prosthetic socket, and automatically adjusting the thickness of said liner model as needed to make up for said difference in size and/or shape;

- an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired;

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a means of providing data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to a manufacturing facility equipped to produce said custom prosthetic liner;

an apparatus for creating at least one custom mold component from said data; and

a molding machine for producing said custom prosthetic liner from a mold incorporating said at least one custom mold component.

Claim 130 (original): The system of claim 129, wherein said socket data is available as a result of the socket manufacturing process.

Claim 131 (original): The system of claim 129, wherein said socket data is obtained by capturing the 3-dimensional shape of the interior of said generic prosthetic socket.

Claim 132 (original): The system of claim 129, wherein said shape capture apparatus for capturing the 3-dimensional shape of said residual limb is also used to capture the 3-dimensional shape of the interior of said generic prosthetic socket.

Claim 133 (original): The system of claim 129, wherein said generic socket is preselected from a group of generic prosthetic sockets, based on its size.

Claim 134 (original): The system of claim 129, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

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Claim 135 (original): The system of claim 129, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is provided to said manufacturing facility via the Internet.

Claim 136 (original): The system of claim 129, wherein said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

Claim 137 (original): The system of claim 129, further comprising a storage means for temporarily storing data associated with the shape of said residual limb and said 3-dimensional electronic liner model.

Claim 138 (original): The system of claim 129, wherein said storage means is selected from the group consisting of a hard disk, a floppy disk, a compact disc or other optical medium, a magneto-optical disk, a magnetic tape, and a PROM or similar other magnetic chip.

Claim 139 (original): The system of claim 129, further comprising a transmission device for remotely transmitting said data associated with said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, to said manufacturing facility.

Claim 140 (original): The system of claim 129, wherein said transmission device is selected from the group consisting of a dial-up modem, a DSL or ISDN modem, a cable modem, a WiFi card, a Bluetooth® card, a WCDMA card, a network interface card (NIC), or a wireless networking card.

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Claim 141 (original): The system of claim 129, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 142 (original): The system of claim 129, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 143 (original): The system of claim 129, further comprising a separate system and computer program for facilitating the automatic configuration and purchasing of a medical device, said separate system and computer program accessible via said processing device.

Claim 144 (original): The system of claim 143, wherein said generic socket may be selected from a database of said system and computer program for facilitating the automatic configuration and purchasing of a medical device.

Claim 145 (original): The system of claim 129, wherein said computer program also generates a viewable 3-dimensional electronic model of said generic prosthetic socket interior.

Claim 146 (original): The system of claim 129, further comprising the ability to use said computer program to select liner materials and liner material properties.

Claim 147 (original): The system of claim 129, further comprising the ability to use said computer program to specify accessories to be included in/on said custom prosthetic liner.

Claim 148 (original): The system of claim 147, wherein the number, location, and orientation of said accessories may also be specified.

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Claim 149 (original): The system of claim 147, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 150 (original): The system of claim 149, wherein said additives include anti-microbial substances.

Claim 151 (original): The system of claim 129, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 152 (original): The system of claim 151, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 153 (original): A system for producing a custom prosthetic liner, comprising:

- a shape capture apparatus for capturing a 3-dimensional shape of an amputee's residual limb;

- a processing device running a computer program for generating a 3-dimensional electronic liner model from said 3-dimensional shape captured by said shape capture apparatus and liner parameters input by user of said system;

- an optional interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model prior to generation of said 3-dimensional electronic liner model, data associated with said 3-dimensional residual limb model subsequently used in generating said 3-dimensional electronic liner model;

- an interface for allowing a user of said system to operate said computer program to specify accessories to be included in/on said custom prosthetic liner;

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optionally, an interface for allowing a user of said system to communicate with a separate system and computer program that facilitates the automatic configuration and purchasing of a medical device;

a means for temporarily storing data associated with a finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both;

a transmission device for allowing data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, to be remotely sent to a manufacturing facility equipped to produce said custom prosthetic liner;

a means at said manufacturing facility for receiving said data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, and for reading said data or converting said data into a readable form;

an apparatus for creating at least one custom mold component from said data;

a molding machine for forming said custom prosthetic liner from a mold incorporating said at least one custom mold component;

once said custom prosthetic liner is completed, a storage means for storing said data associated with said finalized version of said 3-dimensional electronic liner model, said 3-dimensional electronic residual limb model, or both, for future use; and

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a storage system for storing said at least one custom mold component for future use, said storage system including a means for identifying a particular custom mold component with a particular amputee.

Claim 154 (original): The system of claim 153, wherein said the number, location, and orientation of said accessories may also be specified.

Claim 155 (original): The system of claim 153, wherein said accessories are selected from the group consisting of different types of suspension components, reinforcement, bladders (including inflatable bladders), additives, and, sensors.

Claim 156 (original): The system of claim 155, wherein said additives include anti-microbial substances.

Claim 157 (original): The system of claim 153, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 158 (original): The system of claim 157, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 159 (original): The system of claim 153, further comprising an interface for allowing a user of the system to select liner materials and liner material properties.

Claim 160 (original): The system of claim 153, wherein said processing device consists of a device selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 161 (original): The system of claim 153, wherein said data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, is provided to said manufacturing facility via the Internet.

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Claim 162 (original): The system of claim 153, wherein said data associated with said finalized 3-dimensional electronic liner model, said 3-dimensional residual limb model, or both, is transmitted to said manufacturing facility over a local area network (LAN) or wireless local area network (WLAN).

Claim 163 (amended): A system for producing a custom prosthetic liner of flexible polymeric material, comprising:

shape data associated with an amputee's residual limb;

a processing device in conjunction with a computer program for generating a 3-dimensional electronic liner model from said data and liner parameters input by a user of said system;

optionally, an interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired, data associated with said 3-dimensional electronic residual limb model subsequently used in the generating said 3-dimensional electronic liner model;

a means of providing data associated with said 3-dimensional electronic liner, said 3-dimensional electronic residual limb model, or both, to a facility equipped to produce said custom liner;

an apparatus for creating at least one custom mold component from said data; ~~and~~

a mold for receiving and containing an amount of said flexible polymeric material, said mold incorporating said at least one custom mold component; and

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a molding machine for producing said custom prosthetic liner from a said
~~mold incorporating said at least one custom mold component.~~

Claim 164 (original): The system of claim 163, wherein said shape data is in the form of a cast of said residual limb.

Claim 165 (original): The system of claim 164, further comprising an electronic shape capture apparatus that is used to capture a 3-dimensional image of an interior of said cast.

Claim 166 (original): The system of claim 163, wherein said shape data is in the form of measurements of said residual limb.

Claim 167 (original): The system of claim 166, further comprising an interface for allowing a user of said system to input said measurements into said computer program.

Claim 168 (original): The system of claim 163, wherein said processing device is selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 169 (original): The system of claim 163, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

Claim 170 (original): The system of claim 163, wherein electronic data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

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Claim 171 (original): The system of claim 163, wherein electronic data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 172 (original): The system of claim 163, wherein said at least one custom mold component is produced by a computer-controlled machining device.

Claim 173 (original): The system of claim 163, wherein said at least one custom mold component is created from a closed-cell foam material.

Claim 174 (original): The system of claim 163, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

Claim 175 (original): The system of claim 174, wherein said mold cavity is selected based only on its size.

Claim 176 (original): The system of claim 163, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 177 (original): The system of claim 163, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 178 (original): The system of claim 177, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 179 (original): The system of claim 163, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 180 (original): The system of claim 163, further comprising the ability to select liner materials and liner material properties.

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Claim 181 (original): The system of claim 163, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 182 (original): The system of claim 181, wherein the number, location, and orientation of said accessories may also be specified.

Claim 183 (original): The system of claim 181, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 184 (original): The system of claim 183, wherein said additives include anti-microbial substances.

Claim 185 (original): The system of claim 163, further comprising a means of communication with an automated system for configuring and purchasing a medical device.

Claim 186 (amended): A method of producing a custom flexible polymeric prosthetic liner, comprising:

obtaining shape data associated with an amputee's residual limb;

providing a processing device in conjunction with a computer program for generating a 3-dimensional electronic liner model from said shape data and liner parameters input by a user of said system;

optionally, providing an interface for allowing a user of said system to operate said computer program to view and modify a 3-dimensional electronic residual limb model if so desired, data associated with said residual limb model subsequently used in generating said liner model;

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providing data associated with said residual limb shape, said 3-dimensional electronic liner model, or both, to a manufacturing facility equipped to produce said custom liner;

creating at least one custom mold component from said data; and

providing a mold for receiving and containing an amount of flexible polymeric material, said mold incorporating said at least one custom mold component; and

using a molding machine to produce said custom prosthetic liner from a said mold incorporating said at least one custom mold component.

Claim 187 (original): The method of claim 186, wherein said shape data is obtained from an existing cast of said residual limb.

Claim 188 (original): The method of claim 186, wherein said shape data is obtained by producing a cast of said residual limb.

Claim 189 (original): The method of claim 188, further comprising electronically capturing a 3-dimensional image of an interior of said cast and providing electronic data associated therewith to said processing device.

Claim 190 (original): The method of claim 189, wherein said image capturing is done at said manufacturing facility.

Claim 191 (original): The method of claim 190, wherein said cast is sent to said manufacturing facility.

Claim 192 (original): The method of claim 186, wherein said shape data is obtained by producing measurements of said residual limb.

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Claim 193 (original): The method of claim 192, further comprising entering said measurements into said system for use by said processing device.

Claim 194 (original): The method of claim 186, wherein said processing device is selected from the group consisting of a laptop computer, a desktop computer, a pen computer, a pocket personal computer (pocket PC), and a personal data assistant (PDA).

Claim 195 (original): The method of claim 186, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is stored on a machine readable medium and is manually delivered to said facility equipped to produce said custom liner.

Claim 196 (original): The method of claim 186, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is remotely transmitted to said facility equipped to produce said custom liner.

Claim 197 (original): The method of claim 186, wherein data associated with the shape of said residual limb, said 3-dimensional electronic liner model, or both, is transmitted to said facility equipped to produce said custom liner over a local area network (LAN) or wireless local area network (WLAN).

Claim 198 (original): The method of claim 186, wherein said at least one custom mold component is produced from said data.

Claim 199 (original): The method of claim 186, wherein said at least one custom mold component is created from a closed-cell foam material.

Claim 200 (original): The method of claim 186, wherein said at least one custom mold component is a mold core for use with a common mold cavity.

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Claim 201 (original): The method of claim 200, wherein said mold cavity is selected based on its size.

Claim 202 (original): The method of claim 186, wherein said at least one custom mold component is a mold cavity for use with a custom or common mold core.

Claim 203 (original): The method of claim 186, wherein said custom prosthetic liner is manufactured from a silicone, urethane, or thermoplastic elastomer material.

Claim 204 (original): The method of claim 203, wherein said custom prosthetic liner is manufactured from a block copolymer material.

Claim 205 (original): The method of claim 186, wherein a fabric covering is applied to an outer surface of said custom prosthetic liner during the liner manufacturing process.

Claim 206 (original): The method of claim 186, further comprising the ability to select liner materials and liner material properties.

Claim 207 (original): The method of claim 186, further comprising the ability to specify accessories to be included in/on said custom prosthetic liner.

Claim 208 (original): The method of claim 207, wherein the number, location, and orientation of said accessories may also be specified.

Claim 209 (original): The method of claim 207, wherein said accessories are selected from the group consisting of suspension components, reinforcement, bladders (including inflatable bladders), additives, and sensors.

Claim 210 (original): The method of claim 209, wherein said additives include anti-microbial substances.

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Claim 211 (original): The method of claim 186, further comprising a means of communication with an automated system for configuring and purchasing a medical device.